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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,071	08/18/2005	Carola Furiosi	0290-0183PUS1	6940

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EXAMINER
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CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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05/21/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,071	<b>Applicant(s)</b> FURIOSI ET AL.	
	<b>Examiner</b> L. E. Crane	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 4/28/05 and 8/18/05 (Prelim. amdts).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5 and 9-11 is/are rejected.
- 7) ☒ Claim(s) 2,4,6-8 and 12-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/28/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

The Abstract of the Disclosure is objected to because it does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

The Abstract has not been supplied in US format. Appropriate amendment is respectfully requested.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

No claims have been cancelled, claims **1-6, 9-12 and 14** have been amended, the disclosure has not been amended, and new claims **14-19** have been added as per the preliminary amendments filed April 28, 2005 and August 18, 2005. One Information Disclosure Statement (IDS) filed April 28, 2005 has been received with all cited references and made of record.

Claims **1-19** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line **y**, the line number "**y**" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Claims 9-11 are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

The term "use" is found at line 1 of claims 9-11. Appropriate amendment to substitute alternative terminology or other appropriate action is respectfully requested.

Claims 1-8 and 14-19 are objected to because of the following informalities:

In claims 1-8 and 14-19 the preambles are not appropriate for independent and dependent US patent claims. Examiner respectfully requests the preamble of amendment of claim 1 to read -- A compound -- and the preambles of dependent claims to be amended to read -- The compound of claim ... -- or the like.

In claim 1 the last two lines appear to include a proviso. To insure that this proviso is clearly noticed, examiner respectfully suggests a separate line for same.

Appropriate correction is required.

Claims 1, 3 and 5 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3 the term "benzothiophenyl group is equivocal and might be confused with an alternative structure than that intended. Examiner suggests that the term be replaced with the term -- benzothiophen-2-yl -- and/or -- benzothiophen-3-yl -- wherein the intended meanings are unmistakable. See also claims 1 and 5 wherein the same confusion is possible.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by **Sako et al.** (PTO-1449 ref. CA).

Applicant is referred to the **Sako et al.** reference at page 5719, column 2, Scheme 1, compounds labeled 1(d) (N<sup>2</sup>-ethylguanylic acid) as anticipatory of the instant claim.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by **Noonan et al.** (PTO-1449 ref. CB).

Applicant is referred to **Noonan et al.** at page 1302, column 2, Scheme 1, wherein compound 1 (N<sup>2</sup>-butylguanylic acid) anticipates the instant claim.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

Claim 1 is rejected under 35 U.S.C. §103(a) as being unpatentable over either of **Sako et al.** (PTO-1449 ref. CA) and **Noonan et al.** (PTO-892 ref. CB).

The instant claims are directed to N<sup>2</sup>-(C<sub>1-4</sub>) alkylguanylic acids.

**Sako et al.** discloses N<sup>2</sup>-ethylguanylic acid and homologous nucleoside precursors of higher and lower alkyl analogues thereof.

**Sako et al.** does not expressly disclose guanosine nucleotides wherein the N<sup>2</sup> substituent is other than ethyl.

**Noonan et al.** discloses N<sup>2</sup>-butylguanylic acid.

**Noonan et al.** does not expressly disclose N<sup>2</sup>-homologues of the noted guanylic acid.

The Hass/Henze doctrine states that an alkyl homologue of a known compound is prima facie unpatentable in the absence of a showing of unexpected results. The homology between compounds disclosed in the prior art and compounds included within the scope of the noted claims has been established. Therefore, In light of the Hass/Henze doctrine the instant claims are deemed to have been rendered obvious by the disclosure of the noted reference. See In re Hass et al. (CCPA 1944) 141 F2d 122, 127, 60 USPQ 544, 548 and In re Henze (CCPA 1950) 181 F2d 196, 85 USPQ 261.

In view of the Hass Henze Doctrine it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make N<sup>2</sup>-homologues of the compounds disclosed by both **Sako et al.** and **Noonan et al.**

Therefore, the instant claimed compounds, N<sup>2</sup>-(loweralkyl)guanylic acids, would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Claims 2, 4, 6-8 and 12-19 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 3 and 5 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. §112 set forth in this Office action, and if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

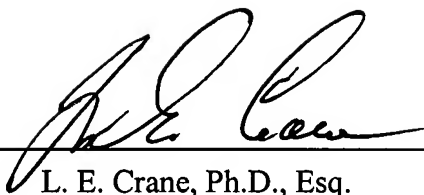
Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Application/Control Number: 10/533,071  
Art Unit: 1623

Page 7

LECrane:lec  
05/13/2007

A handwritten signature in black ink, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.

Patent Examiner

Technology Center 1600